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DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District
Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

April 17, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Rachel Ben-Shaul
President
Agrexco (U.S.A.) Limited
150-12 132 Avenue
Jamaica, NY 11434

Ref: NYK 2002-23

Dear Ms Ben-Shaul:

The Food and Drug Administration (FDA) has information which shows that your firm violated the Federal Food, Drug and Cosmetic Act.

On January 30, 2002, FDA sampled a shipment of fresh lettuce offered for Import on January 28, 2002 by your firm under Entry Number EH1-0078836-1 and found the shipment had been partially distributed. The product was at the premises of a consignee who did not hold it intact. As the Importer of record it is your responsibility to hold the product intact until it is released.

The action taken by your firm is a violation of 21CFR 1.90, which requires an importer to hold an entry intact pending receipt of a "May Proceed" or "Release Notice" form FDA. A "Release" by the U.S. Customs Service is a conditional release, which merely permits you to take possession of the shipment. When other Federal agencies, such as FDA also exercise jurisdiction over a product offered for importation, its release must be obtained before any of the product may be legally distributed.

Failure to promptly correct this violation and prevent future premature distribution of imported product may result in requiring that future shipments be held in secured storage. Secured storage will be under supervision and direction of U.S. Customs Service, such as in a bonded warehouse. You will be responsible for all costs incurred in secured storage.

Failure to promptly correct this violation and prevent future violations may also result in

additional regulatory action without further notice, such as seizure, injunction, or detentions without physical examination, to ensure that the product is held intact until released by FDA.

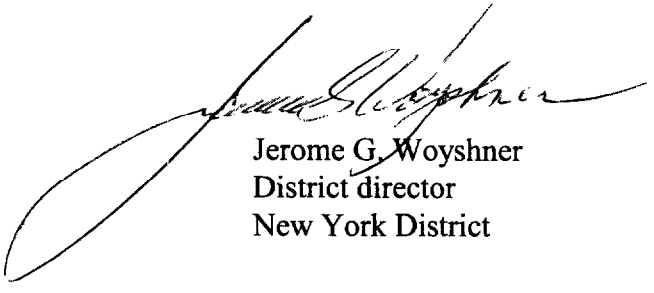
In addition, we are requesting U.S. Customs Service to order redelivery of the part of the shipment that was distributed (notice included).

Within fifteen (15) working days of receipt of this letter, please notify our office in writing of the specific steps you have taken to correct this violative situation, including an explanation of each step being taken to prevent reoccurrence of the violation.

A copy of this letter, except for confidential, personal or commercial information will be placed on public display no earlier than (15) days after the date of this letter. Your response will also be on public display with any confidential, personal or commercial information purged.

Your response should be addressed to the Food and Drug Administration, Attention: Helen R. Jacobs – Compliance Officer, 158-15 Liberty Avenue, Jamaica NY 11433 (telephone 718-340-7000 extension 5681)

Sincerely yours,



Jerome G. Woyshner
District director
New York District